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105TH CONGRESS
1ST SESSION

H. R. 2972

To direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 8, 1997

Mr. STARK introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To direct the Secretary of Health and Human Services to establish a continuous quality improvement program for providers that furnish services under the Medicare Program to individuals with end stage renal disease, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "ESRD Continuous Quality Improvement Program Act of 1997".

SEC. 2. ESTABLISHMENT OF CONTINUOUS QUALITY IMPROVEMENT PROGRAM FOR ESRD FACILITIES UNDER MEDICARE.

Section 1881 of the Social Security Act (42 U.S.C. 1395rr) is amended by adding at the end the following new subsection:

"(h)(1)(A) Not later than 1 year after the date of the enactment of this subsection, the Secretary shall establish a quality improvement program (hereafter in this subsection referred to as the 'CQI Program') for providers of services and renal dialysis facilities under this section. In establishing the CQI Program, the Secretary shall consult with representatives of providers of services and renal dialysis facilities (including facility administrators, nephrologists, dietitians, social workers, and nurses), patients of such providers and facilities, and quality improvement experts.

"(B) Under the CQI Program—

"(i) the network administrative organizations (as defined in paragraph (7)) shall provide information, training, and technical assistance described in paragraph (2);

"(ii) the Secretary shall establish and publish in ESRD Core Indicators as described in paragraph (3);

"(iii) the Secretary shall collect and analyze data from providers and facilities as described in paragraph (4);

"(iv) the Secretary shall identify and reward outstanding providers and facilities as described in paragraph (5); and

"(v) the Secretary shall identify and provide for additional training to providers and facilities in need of such training as described in paragraph (6).

"(2) Network administrative organizations shall perform the following functions:

"(A) Provide for the routine and timely measurement and statistical evaluation, and feedback to providers of services and renal dialysis facilities, of the processes and outcomes of care for kidney transplant, hemodialysis, and peritoneal dialysis patients, using, among other data, the ESRD Core Indicators established under paragraph (3).

"(B) Disseminate recommended clinical practices based on practice guidelines or clinical algorithms.

"(C) Provide training in quality improvement to the staffs of network administrative organizations to assist the organizations in providing training and as-

sistance to providers of services and renal dialysis facilities.

"(D) Conduct regional and national peer review of dialysis providers.

"(E) Provide technical assistance for quality improvement efforts and identify quality improvement activities to reflect evolving needs of patients and facilities.

"(F) In consultation with the Work Group (as defined in paragraph (7)), provide guidance to providers of services and renal dialysis facilities on the collection and calculation of the core indicator measures.

"(G) Make information and materials under the program available for the use of—

"(i) facilities and providers in Medicare+Choice organizations;

"(ii) facilities and providers that do not receive payments under this title; and

"(iii) private payers of services for end stage renal disease patients.

"(3) Not later than 1 year after the date of the enactment of this subsection, the Secretary shall publish in the Federal Register the ESRD Core Indicators established as follows:

"(A) The Work Group shall define and periodically update ESRD Core Indicators.

"(B) The ESRD Core Indicators defined under paragraph (A) may include patient outcome measures based upon the following types of indicators (subject to the establishment of unique measures for kidney transplantation centers) and such other indicators as the Work Group considers appropriate:

"(i) Adequacy of dialysis.

"(ii) Adequacy of nutrition.

"(iii) Correction of anemia and average per patient dosage of anti-anemia medications.

"(iv) Case-adjusted standardized mortality.

"(v) Case-adjusted hospitalization ratios and average length of hospital stay.

"(vi) Adequacy of blood pressure control.

"(vii) Successful vocational maintenance or rehabilitation.

"(viii) Referral for transplantation or self-treatment at home.

"(ix) Appropriate administration of clinical lab tests.

"(C) To the greatest extent possible, the ESRD Core Indicators shall be developed in conjunction with any relevant quality improvement goals estab-

lished by the Secretary or by network administrative organizations which are in effect as of the date of the enactment of this paragraph.

"(D) The network administrative organizations, individual renal dialysis facilities, and individual providers of services shall be encouraged to establish additional independent patient-specific and physician-specific or facility-specific core indicators.

"(4)(A)(i) Not later than 2 years after the date of the enactment of this subsection, the Secretary shall establish a standard information management system (hereafter in this paragraph referred to as "SIMS") to promote the electronic transfer of data obtained under the CQI Program among providers, facilities, the Secretary, and network administrative organizations. The Secretary shall provide for technical assistance in the use of the SIMS and for the development (or purchase) and distribution of appropriate electronic software for access to the SIMS.

"(ii) Under the SIMS—

"(I) a facility or provider of services shall contribute data to support the CQI Program; and

"(II) network administrative organizations shall use data entered into the SIMS to generate clinical profiles on the performance of facilities, based on

the ESRD Core Indicators, and shall monitor trends relevant to performance of facilities.

"(iii) The SIMS shall be available to all network administrative organizations and to all facilities or providers of services.

"(B) The Secretary shall—

"(i) use the SIMS to collect with such frequency as the Work Group determines appropriate (but not less frequently than bi-annually) unadjusted data on all patient outcomes required to compute ESRD Core Indicators—

"(I) from each provider of services and renal dialysis facility; and

"(II) from physicians providing services to individuals determined to have end stage renal disease under this section;

"(ii) combine the data collected under clause (i) on individual patients into aggregate data for each provider of services and renal dialysis facility and for each such physician, after taking into account relevant factors (including age, gender, race, income, severity of illness, and other morbidities);

"(iii) adjust the data combined under clause (ii) to establish comparisons of the core indicator measures of—

"(I) each provider and facility with other providers and facilities ; and

"(II) each such physician with other such physicians in the network area and the nation;

"(iv) create a national core indicator measures database from the data combined and adjusted under this subparagraph;

"(v) using unique identifiers to preserve patient confidentiality and confidentiality between providers and facilities, report—

"(I) each provider's and facility's combined and adjusted data under this subparagraph to the provider or facility and each such physician's combined and adjusted data under this subparagraph to the physician;

"(II) how that provider and facility compares in various CQI indicators to other providers or facilities in the same network and in all networks and how that physician compares in various CQI indicators to other physicians; and

"(III) such data to the network administrative organization for the network area in which the provider, facility, or physician is located; and

"(vi) provide the data collected under clauses (i), (ii), and (iii) to the United States Renal Dialysis System and other entities engaged in efforts to improve the quality of services for renal patients.

"(5)(A) For each of three years beginning after December 31, 2001, the Secretary shall identify those dialysis facilities and physicians that are 2 standard deviations above the national norm for a preponderance of ESRD Core Indicators on a case severity adjusted basis for 2 consecutive reporting periods (covering in the aggregate at least 1 year), and shall designate such dialysis facilities and providers as 'Medicare Dialysis Providers of Achievement'.

"(B) Upon request by the network administrative organization for the end stage renal disease network area in which the facility is located, each Medicare Dialysis Provider of Achievement designated under subparagraph (A) shall provide a report on the clinical process and monitoring techniques which in the facility's opinion are most responsible for the facility's successful outcomes to the network administrative organization for use as a model for other facilities and physicians in the network area.

"(C) The Secretary shall maintain and update a list of Medicare Dialysis Providers of Achievement. Not later than March 1 of each of the three years after 2001, the

Secretary shall publish such list in the Federal Register. The appropriate network administrative organization shall publicly award such providers of achievement at an annual meeting.

"(6)(A) If the Secretary or the network administrative organizations for the network area in which a facility or physician is located determines that the dialysis facility or physician is 2 standard deviations below the national norm for a preponderance of ESRD Core Indicators on a case severity adjusted basis for 2 consecutive reporting periods (covering in the aggregate at least 1 year), the Secretary or network administrative organization shall notify the facility or physician of such determination.

"(B) In the case of a facility notified under subparagraph (A), the network administrative organization for the network area in which the facility is located, in conjunction with the facility, shall develop strategies to improve the provision of services at the facility and shall provide appropriate training in CQI Program processes to the facility. Such network administrative organization shall review the quality of service provided by physicians at such facility for purposes of identifying those physicians that require training in CQI Program processes.

"(C) In the case of a physician notified under subparagraph (A), the network administrative organization

for the network area in which the physician is located, in conjunction with the physician, shall develop strategies to improve the provision of services by the physician, and shall provide appropriate training in CQI Program processes to the physician.

"(D) If the Secretary finds that the facility or physician has not made a good faith effort to improve its performance under this paragraph, the network administrative organization for the network area in which the facility or physician is located—

"(i) in the case of a facility, subject to subparagraph (E), may recommend that the Secretary terminate or withhold certification of the facility for purposes of payment for services furnished to individuals with end stage renal disease; and

"(ii) in the case of a physician, may recommend to the Secretary—

"(I) further investigation of the physician; or

"(II) such other actions as the network determines appropriate.

"(E) In the case of a facility for which the network administrative organization for the network area in which the facility is located proposes to recommend that the Secretary terminate or withhold certification of the facility

under subparagraph (D), the network administrative organization shall profile physicians furnishing services at the facility to determine shared facility/physician responsibility for the termination.

"(7) As used in this subsection:

"(A) The term 'network administrative organization' means the organizations described in subsection (c)(1)(A).

"(B) The term 'Work Group' means an ESRD Core Indicators Work Group appointed by the Secretary and composed of representatives of providers of renal services, patient advocacy groups, the network administrative organizations, the United States Renal Data System, patient vocational and rehabilitation organizations, quality improvement organizations, and the Secretary.".

SEC. 3. RESPONSIBILITIES OF ESRD PROVIDERS, FACILITIES, AND NETWORKS.

(a) PARTICIPATION IN CQI PROGRAM AS REQUIREMENT FOR MEDICARE PAYMENT FOR PROVIDERS AND FACILITIES.—

(1) IN GENERAL.—Section 1881(b)(1) of the Social Security Act (42 U.S.C. 1395rr(b)(1)) is amended by striking the period at the end of the second sentence and inserting the following: ", and

a requirement that the provider of services or renal dialysis facility meet the requirements of subsection (i) with respect to participation in the CQI Program under subsection (h).".

(2) SPECIFIC REQUIREMENTS DESCRIBED.—Section 1881 of such Act (42 U.S.C. 1395rr), as amended by section 2, is amended by adding at the end the following new subsection:

"(i)(1) For purposes of subsection (b)(1), each provider of services or renal dialysis facility shall take such actions as may be required for the provider or facility to participate in the CQI Program under subsection (h), including the following:

"(A) Establishing a CQI team described in paragraph (3) which will have primary responsibility for ensuring that the provider or facility meets the requirements of this paragraph.

"(B) Developing and operating a quality improvement program consistent with the requirements of the CQI Program under subsection (h).

"(C) Furnishing information required for the collection and reporting of data under subsection (h)(4).

"(D) Posting in a prominent location the data for a provider or facility described in subsection

(h)(4)(B) and distributing a copy of the data to each patient.

"(E) Taking any other actions which the Secretary or the network administrative organization may require in the administration of the CQI Program.

"(2)(A) If the Secretary determines that a facility or provider has failed to report data under the CQI Program or has knowingly and willfully reported false data under the CQI Program, the Secretary may terminate or withhold certification of the facility or provider for purposes of payment for services furnished to individuals with end stage renal disease.

"(B) In the case of a facility or provider whose certification is terminated or withheld by the Secretary under subparagraph (A), if the Secretary determines that information submitted by such facility or provider is not false, the bar to certification under such subparagraph shall not apply.

"(3) The CQI team of a provider of services or renal dialysis facility shall—

"(A) consist (at a minimum) of the provider's or facility's medical director, director of nursing, social worker, dietitian, chief technician, together with

representatives of the provider's or facility's patients;

"(B) periodically hold meetings, which shall be open to patients and personnel of the provider or facility, and make minutes of the meetings available to patients and personnel for a reasonable period of time;

"(C) designate one of its members as the director of continuous quality improvement for the provider or facility and coordinator with the Network on CQI issues;

"(D) consistent with the standards of the CQI Program under subsection (h), promote clinical practice guidelines or algorithms for the use of the provider or facility; and

"(E) take any other actions which may be required to ensure the full participation of the provider or facility in the CQI Program under subsection (h).".

(b) RESPONSIBILITIES OF ESRD NETWORK ADMINISTRATIVE ORGANIZATIONS.—

(1) ASSISTANCE IN OPERATION OF PROGRAM.—Section 1881(c)(2)(B) of such Act (42 U.S.C. 1395rr(c)(2)(B)) is amended by inserting after "(B)" the following: "assisting the Secretary in the

administration of the CQI Program under subsection (h) and (consistent with the operation of such Program)".

(2) COLLECTION AND DISSEMINATION OF CQI DATA.—Section 1881(c)(2) of such Act (42 U.S.C. 1395rr(c)(2)) is amended—

(A) by striking "and" at the end of subparagraph (G);

(B) by redesignating subparagraph (H) as subparagraph (I); and

(C) by inserting after subparagraph (G) the following new subparagraph:

"(H) collecting and making public data on facilities and providers generated under the CQI Program under subsection (h) (in accordance with standards established by the Secretary in consultation with representatives of providers, facilities, and patients) and auditing samples of such data to ensure its accuracy; and".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished 1 year on or after the date of the enactment of this Act.

SEC. 4. STUDY OF FINANCIAL IMPACT OF CQI PROGRAM ON ESRD NETWORK ADMINISTRATIVE ORGANIZATIONS.

Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall—

(1) analyze the financial impact of the establishment of the ESRD Continuous Quality Improvement Program under section 1881(h) of the Social Security Act (as added by section 2) on ESRD network administrative organizations under section 1881(c) of such Act, and

(2) submit to Congress such recommendations as the Secretary considers appropriate to assist the organizations with meeting their responsibilities under such Program.

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